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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,563	11/26/2003	Charles E. Seeney	089701-00002	1254

7590 06/14/2005

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EXAMINER

LE, HOA T

ART UNIT	PAPER NUMBER
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1773

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/724,563

Applicant(s)

SEENEY ET AL.

Examiner

H. T. Le

Art Unit

1773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) 45-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date July '04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-44, drawn to a nanosphere containing coated nanoparticle, classified in class 428, subclass 323.
 - II. Claims 45-55, drawn to process of coating particles, classified in class 427, subclass 212.
 - III. Claims 56-66, drawn to a coated nanoparticle, classified in class 428, subclass 407.
 - III. Claims 67-71, drawn to a product of double coating, classified in class 428, subclass 407.
2. The inventions are distinct, each from the other because of the following reasons:
 - a. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another materially different process such as emulsion.
 - b. Inventions I and III are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product

(MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a contrast agent and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

c. Inventions I and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the shell encapsulating the nanoparticles can comprise a biocompatible material and thus removes the requirement of the presence of a bioshell. The subcombination has separate utility such as a contrast agent.

d. Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another materially different process such as emulsion.

e. Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another materially different process such as emulsion.

f. Inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the shell encapsulating the nanoparticles can comprise a biocompatible material and thus removes the requirement of the presence of a bioshell. The subcombination has separate utility such as a contrast agent.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Applicant's Representative, Attorney Lawrance Grable on March 14, 2005, a provisional election was made with traverse to prosecute the invention of group I, claims 1-44 and 56-66. Affirmation of this election must be made by applicant in replying to this Office action. Claims 45-55 and 67-71 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(a) The specification fails to provide an adequate description as to how to make the claimed nanosphere. How does the nanosphere form? What mechanism effects the nanoparticles to form a nanosphere? How is the shape of the nanosphere achieved? What is the material of the shell/wall/layer that forms the nanosphere? How does the nanosphere contain the nanoparticles?

(b) The specification fails to provide a definition for the term “cell adhesion factors”. What are the “factors”? Are the factors a chemical agent or a physical mechanism? In addition, the specification fails to provide an adequate description as to how to obtain a support of cell adhesion factors for the bio-compatible shell.

8. Claims 1-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and the invention. It is entirely unclear from the specification as to: How does the nanosphere form? What mechanism effects the nanoparticles to form a nanosphere? How is the shape of the nanosphere achieved? What is the material of the shell/wall/layer that forms the nanosphere? How does the nanosphere contain the nanoparticles?

9. Claims 8, 11, 14, 18, and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 8, 14, 18, it is unclear what is meant by “erodable” polymer. Does it mean decomposable? All organic polymers are decomposable.

In claims 11 and 21, it is unclear what is meant by “cell adhesion factors”. The meaning of such term is not defined in the specification as discussed above.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 1-44 are rejected under 35 U.S.C. 102(a) as being anticipated by pioneers in the art as disclosed by Pankhurst et al. in the article entitled “Application of magnetic nanoparticles in biomedicine” (“Parkhurst”) and/or Tartaj et al in the article “The Preparation of magnetic nanoparticles for applications in biomedicine” (“Tartaj”).¹

Examiner’s comments: The publication date of these articles is the same date as the effective filing date of the instant application (June 18, 2003). However, magnetic nanoparticles discussed in these articles are particles that have been made and known in the

¹ Copy of this article has been provided by Applicant.

art prior to the publication of these articles. Therefore, information revealed in these articles qualify as a prior art.

Claims 1-3: Pankhurst and Tartaj disclose that nanoparticles having a biocompatible coating have been made and known since 1997. See Parkhurst, page R172 section 4.2. Note the reference to footnotes 42-44 and 46-52; papers pertained to these footnotes were published from 1997 to 2002. Also see Tartaj, page R183, left column, third full paragraph. Pankhurst et al disclose magnetic nanoparticles of “few nanometers” (Parkhurst, page R167, left column, first 5 lines). And at this size (under 15 nm), the nanoparticles are monodomain (see Tartaj, page R182, right column, last 8 lines).

Claims 4-5: See Pankhurst, page R172, right column, first paragraph; or Tartaj, page R183, left column, third full paragraph.

Claims 6-7: See Pankhurst, page R172, right column, figure 6; or Tartaj, p. R191, section 3.2.3.

Claim 8: The nanoparticles have been known to be stabilized with water soluble polymers (see Tartaj, p. R187, left column, first paragraph) which is “aqueously erodable”.

Claims 9-10: See Pankhurst, page R172, right column, figure 6; or Tartaj, p. R191, section 3.2.3.

Claim 11: Parkhurst discloses magnetic nanoparticles whose surfaces are functionalized to enable cell attachment for the nanoparticles are old (see Parkhurst, page R172, left column, last full paragraph. Note footnotes 42-44). Cell attachment is disclosed by Tartaj as old.

See Tartaj, p. R183, left column, third full paragraph, lines 5-8.

Claim 12: See rejections to claims 1-3 and 9.

Claims 13-16: See rejection to claims 1-8.

Claims 15, 17 & 18: See Parkhurst, p. R171, section 4.1

Claims 19-20: See rejections to claims 1-3 and 17-18.

Claims 21-22: See rejections to claims 1 and 11.

Claim 23: See Tartaj, p. R182, right column, last paragraph.

Claims 24-44: See rejections to claims 1-23 above. Note that claims 24-44 are product-by-process claims, and the product limitations as recited in these claims are met by the discussions in the articles by Pankhurst and Tartaj as set forth above.

In addition, with regarding to claims 24-36, nanospheres made by a vapor method are disclosed as old in the art by Tartaj. See Tartaj, p. R188, section 3.1.2. With regarding to claims 37-44, nanospheres made by a precipitation method are revealed as old by Tartaj. See Tartaj, p. R185, section 3.1.1.

12. Claims 1-4, 14, 23, 24 and 37 are rejected under 35 U.S.C. 102(a) as being anticipated by either Wilhelm et al ("Intracellular uptake of anionic superparamagnetic nanoparticles as a function of their surface coating").

Claims 1-4 and 23: See page 1002, sections 2.1.2, 2.2, and 2.4 (first paragraph, lines 4-8).

Section 2.1.2 reveals that the magnetic particles are monodomain and superparamagnetic.

Claim 14: See section 2.3. Dextran is "erodable".

Claims 24 and 37: See rejection to claims 1-4. These claims are product-by-process claims, and the product limitations recited in these claims are met by the teaching of Wilhelm as discussed immediately above.

13. References not relied upon are cited as art of interest.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to H. T. Le whose telephone number is 571-272-1511. The examiner can normally be reached on 10:00 a.m. to 6:30 p.m., Mondays to Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on 571-272-1284. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



H. T. Le
Primary Examiner
Art Unit 1773